## REMARKS

Claims 7-26 are pending, claims 7-18 and 24-26 are withdrawn from consideration, and claims 19-23 are rejected.

***Objection to the drawings***

The Examiner objects to Figure 1 because one of the sequences is not identified (perhaps it belongs to Figure 2a). Applicant provides herewith a corrected Figure 1 removing the sequence that belongs with Figure 2a. Further, Figure 2A is corrected to provide the entire sequence on different sheets than Figure 1.

***Objection to the specification***

The Examiner objects to the specification because the title is allegedly not descriptive and because Herceptin® is not capitalized. The Examiner suggests that the title be changed to "Detection of MAL2 protein in carcinoma diagnosis." Applicant herein amends the title as suggested and capitalizes Herceptin® in each instance.

***Rejection under 35 U.S.C. 102***

The Examiner rejects claims 19-23 as allegedly anticipated by Monahan *et al.* (U.S. Patent Publication 2003/0087250) and Ruben *et al.*, (WO01/36440 A1). Applicant restectfully traverses. Applicant submits that it is a fundamental principle of the patent law that in order for a reference to be prior art under 35 U.S.C. 102, the reference must enable its alleged teachings. That is, to anticipate, the prior art must be enabling – i.e., it must "enable one of ordinary skill in the art to make the invention without undue experimentation." This enablement standard is admittedly different from an applicant's 35 U.S.C. §112 enablement requirement that requires enabling both *making and using* an invention. However, the Federal Circuit appears to require anticipatory prior art to enable practicing the claimed method. *See, Impax v. Aventis Pharmaceuticals* (Fed. Cir. 2008).

The legal standard

Whether the prior art enables its alleged teachings is a question of law, but it is based on underlying factual findings. In close cases, the important factual finding is the amount of experimentation that would have been necessary. Applying *Wands* factors, the Federal Circuit recently agreed that the prior reference was not enabling in *Impax v. Aventis Pharmaceuticals,* Case No. 07-1513 (Fed. Cir. 2008) because the prior art patent disclosed a formula encompassing hundreds or thousands of compounds for the treatment of several diseases. However, in view of the prior art disclosure, excessive experimentation would have been required to use one compound, riluzole, to treat one condition, ALS.

Regarding Monahan *et al.*

Monahan *et al.* teach at paragraph [0068] that Table 1 provides markers that are over-expressed in ovarian cancer cells compared to normal ovarian cells. Table 1 on pages 7-10 lists hundreds of proteins, each of which is alleged to be a marker of ovarian cancer. However, Monahan *et al.* do not provide any data showing that the plethora of proteins listed in Table 1 is a marker for ovarian cancer. Applicant refers to the Examples on pages 40-41 where the total expression levels of ovarian cancer cell clones are compared to normal cell clones, and after selecting higher expressing ovarian cancer cell clones, the protein-encoding transcript sequences were determined. (*See*, paragraph [0335]) Taqman expression levels are only provided for OV88 protein on page 41. Accordingly, Monahat *et al.* do not provide any evidence that any one of the remaining hundreds of proteins listed in Table 1 is either over-expressed or under-expressed in ovarian cancer. Therefore, Monahan *et al.* fail to teach that any one of the remaining proteins of Table 1 may be used as an ovarian cancer marker for diagnosis. In short, one of ordinary skill in the art could not diagnose cancer by detecting one protein, MAL2 expression, without undue experimentation in view of the teachings of Monahan *et al.*

Regarding Ruben *et al.*

Ruben *et al.* provide a purely speculative disclosure of a vast number of proteins and their possible roles in diagnostic and therapeutic methods. Applicant refers to pages 28-31 where Ruben *et al.* teach that the Mal-a protein plays a role in a vast number of different cancers,

immune system disorders, neurodegenerative disorders, behavioral disorders and other diseases. However, Ruben *et al.* provide no evidence of the role of the Mal-a protein in any disease. Regarding cancer, Ruben *et al.* teach that Mal-a is present at elevated levels in a number of cancers including cancers of the ovary, colon, lung and prostate. However, Ruben *et al.* provide absolutely no data to substantiate this allegation. Ruben *et al.* only provide examples that are merely details of methods that may be performed and are purely speculative. Therefore, Ruben *et al.* fail to teach that MAL2 may be used as an ovarian cancer marker for diagnosis. In short, one of ordinary skill in the art could not diagnose cancer by detecting one protein, MAL2 expression, without undue experimentation in view of the teachings of Ruben *et al.*

## FEES

It is believed that no additional fees are necessary in connection with the present submission; however, should this be in error, authorization is hereby given to charge Deposit Account No. 11-1153 for any underpayment or to credit any overage.

## CONCLUSION

It is believed that all of the claims are patentable and early notification as such is earnestly solicited. If any issues may be resolved by way of telephone, the Examiner is invited to call the undersigned at the telephone number indicated below.

Respectfully submitted,

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